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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,370	10/03/2001	Randall K. Holmes	33,383-00	8568
38199	7590	06/25/2004		
HOWSON AND HOWSON CATHY A. KODROFF ONE SPRING HOUSE CORPORATE CENTER BOX 457 SPRING HOUSE, PA 19477			EXAMINER PORTNER, VIRGINIA ALLEN	
			ART UNIT 1645	PAPER NUMBER

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/806,370

Applicant(s)

HOLMES ET AL.

Examiner

Ginny Portner

Art Unit

1645

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED **FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.** Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. **ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).**

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☒ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: the amendment raises new issues and was not entered.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: 12 and 38.

Claim(s) rejected: 1-17 and 24-43.

Claim(s) withdrawn from consideration: 1-17, 28-37 and 39-43subparagraphs.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 2. NOTE: see attachment. A new combination of claim limitations is set forth in proposed claims 12 and 38.

*Response to Amendment*

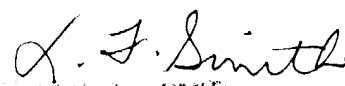
1. For at least the following reasons the Amendment After Final has not been entered:
  - a. Claims 12 and 38 are proposed to recite the phrase “at least one polynucleotide sequence, sets forth the claims in independent form, and recite in the alternative a polynucleotide for HSV gD2 and a polynucleotide for a mutant cholera holotoxin to define antigenic compositions for the induction of an immune response.
    - i. Antigenic compositions that only comprise a single HSV gD2 polynucleotide has not been previously considered on the record in the Final Office action.
    - ii. Original descriptive support for the administration of only HSV gD2 polynucleotide without an adjuvant mutant holotoxin in the composition may be not described in the instant specification that is directed to combination compositions of a mutant cholera holotoxin together with an antigen.
    - iii. Antigenic compositions that only comprise a polynucleotide encoding a mutant cholera holotoxin, that may be optionally combined with the polynucleotide for HSV gD2 polynucleotide that is in a plasmid, has not been previously examined in the Final Office Action, and the proposed Amendment of the claims After Final therefore raises New Issues.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp  
June 22, 2004

  
LYNETTE R. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600